



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,894	06/20/2001	Gregory S. Shelness	9151.18	4865

20792 7590 09/19/2002

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/19/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/885,894

Applicant(s)

Shelness

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1642

1. Claims 1-43 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1. Claims 1-22 are drawn to a lipoprotein compound delivery particle comprising a lipophilic compound, classified in Class 530, subclass 300+.

Group 2. Claims 1-23 are drawn to a lipoprotein compound delivery particle comprising an amphipathic compound, classified in Class 530, subclass 300+.

Group 3. Claims 24-34 are drawn to a composition comprising a plurality of lipoprotein delivery particles comprising a lipophilic compound classified in Class 530, subclass 300+.

Art Unit: 1642

Group 4. Claims 24-34 are drawn to a composition comprising a plurality of lipoprotein delivery particles comprising an amphipathic compound, classified in Class 530, subclass 300+.

Group 5. Claims 35-38 are drawn to a method of delivering a compound to a subject in need comprising administering a lipoprotein delivery particle comprising a lipophilic compound, classified in class 514, subclass 2+.

Group 6. Claims 35-38 are drawn to a method of delivering a compound to a subject in need comprising administering a lipoprotein delivery particle comprising an amphipathic compound, classified in class 514, subclass 2+.

It is noted that the claim 39 of the instant application have been determined to be a linking claim. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 39. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer

Art Unit: 1642

applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 7-75. Claims 39-43 are drawn to a covalent conjugate comprising a truncated apolipoprotein wherein the truncated apolipoprotein is one of apoB6 through apoB74, each of which is a distinct invention. Applicant is required to elect a single invention (this is not a species election) for examination on the merits.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-4 and 7-75 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Inventions 5-6 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-4, 7-75 and 5-6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the lipoprotein compound delivery particle and the covalent conjugate as claimed can be used in a materially different process

Art Unit: 1642

such as affinity chromatography or the production of antibodies to the constituents of the compound.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups 1 and 2 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising heterologous moieties with different structures and functions wherein the heterologous moieties are (a) peptide (claim 3), (b) antibody (claims 4-6).

6. Groups 1 and 2 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising truncated apoB proteins with different structures and functions wherein the proteins are (a) apoB74 (claim 9), (b) ApoB 19.5 (claim 10), (c) mature apoB (claims 11-13).

7. Groups 1 and 2 are further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising polar lipids with different structures and functions wherein the polar lipids are one, or a combination of the 7 polar lipids recited in claim 14. It is noted that by factorial analysis the claim is drawn to 5040 separate and distinct combinations of polar lipids. Applicant is required to elect a specific single of combination of polar lipids for examination.

8. Groups 1 and 2 are further subject to election of a single disclosed species.

Art Unit: 1642

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising neutral lipids with different structures and functions wherein the polar lipids are one or a combination of the four neutral lipids recited. It is noted that by factorial analysis the claim is drawn to 24 separate and distinct combinations of polar lipids. Applicant is required to elect a specific single of combination of polar lipids for examination.

9. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising particles with different structures and functions wherein the particles are (a) discoidal particle (claim 18), (b) a small emulsion particle (claims 19-20), © a large emulsion particle (claims 21-22).

10 Claim 35 is generic to a plurality of disclosed patentably distinct species comprising modes of administration which differ least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the modes are (a) parental injection (claim 36), (b) intravenous injection (claim 37), (c) topical administration (claim 38).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Art Unit: 1642

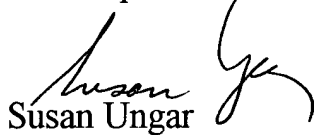
12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
September 10, 2002